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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/586,261	02/28/2007	Sunil Kumar	0641-0283PUS1	4714

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EXAMINER	
SELLMAN, CACHET I	

ART UNIT	PAPER NUMBER
1715	

NOTIFICATION DATE	DELIVERY MODE
01/24/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/586,261	KUMAR ET AL.	
	Examiner	Art Unit	
	CACHET I. SELLMAN	1715	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 November 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *40-54 and 60-74* is/are pending in the application.

4a) Of the above claim(s) *55-59 and 75-76* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *40-50,53,54,60-70,73 and 74* is/are rejected.

7)☒ Claim(s) *51-52, 71 and 72* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 July 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/20/2008 and 9/7/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I, claims 40-54 and 60-74 in the reply filed on 10/21/2010 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Applicants argue there is no burden for examining all three groups. However, the previous action was a **lack of unity** and since Smart et al. discloses the special technical feature of one of the group of claims, there is no unity in special technical feature between Groups I, II, and III.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 40-46, 48-49, 53-54, 60-66, 68-69, and 73-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smart et al. "New Approaches to Metal Ceramic and Bioceramic Interfacial Bonding".

As to claims 40 and 60, Smart et al. discloses a process for applying bioceramic coatings onto implantable devices which aid in bone growth (see Introduction, pp293-294). Smart et al. discloses the importance of the bonding between the metallic surface of the implantable devices and the bioceramic coating which can be enhanced by

providing functionally graded coatings (see section 5.0, pg 305 and 314). Smart et al. teaches exposing the surface of the implant to a plasma gas containing a reactive hydroxylating oxidant, hydrogen peroxide, in order to form a graded hydrolyzed silica coating on the substrate which improves the activity of the surface and induces hydroxyapatite growth (see Section 6.0 hydrolysed surface layers). Smart et al. further states the level of hydration can be controlled by the vol % of hydrogen peroxide (see section 6.0 page 314).

Smart et al. fail to teach adjusting the vapor pressure of the hydroxylating oxidant species in order to form a gradient layer. However, Smart et al. does suggest the hydroxylating species controls the level of hydration of the silica layer and the desire to have the outer surface contain a high concentration of SiOH groups for increased reactivity (see pages 313-314) therefore the vol % of the hydrogen peroxide layer is a result effective variable. It would have been obvious to one having ordinary skill in the art to adjust the vapor pressure of the hydrogen peroxide since the vapor pressure affects the volume % of the hydrogen peroxide ($V_x = V_{tot} * P_x/P_{tot}$) during the exposure in order to form the graded layer which improves the adhesion between the different layers and have the highest level of hydration on the outer layer in order for the hydroxyapatite layer to successfully form (see section 6.0).

As to claims 41-42 and 61-62, the species is hydrogen peroxide (see section 6.0 pp 313-314).

As to claims 43 and 63, Smart et al. does not state that the hydrogen peroxide vapor pressure is increased over time. However, as stated above, the amount of hydrogen peroxide controls the level of hydration of the silica layer, therefore; it would have been obvious to one having ordinary skill in the art to gradually increase the vapor pressure of the hydrogen peroxide for the duration of exposure in order to form the graded layer and to achieve the highest level of hydration on the outer layer in order for the hydroxyapaptite layer to successfully form on the implant surface as desired by Smart et al (see pages 313-314).

As to claims 44 and 64, Smart et al. discloses the implant can be made of titanium, titanium alloy, or cobalt-chromium (see section 5.0 pg 305).

As to claims 45 and 65, a hydroxyapatite coating is applied over the hydrolyzed silica coating (see section 7.0 pg 314).

As to claims 46 and 66, prior to exposing the implant to the hydrogen peroxide plasma, a silicon oxide layer is formed by using an organosilane and air/ water vapor plasma to form a silica coating (see section 3.0, pp 313-314) and varying the concentration (see page 307).

As to claims 48, 49 and 68-69, the organosilane is tetraethoxysilane (see pg 313-314).

As to claims 53 and 73, the process is carried out without being exposed to air therefore the process is performed in a continuous manner (see section 5.0 page 305).

As to claims 54 and 74, a hydroxyapatite coating is formed over the graded silica coating (see section 7.0 pg 314).

4. Claims 47, 50, 67, and 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smart et al. as applied to claim 46 and 66 in view of Stevenson et al. "XPS studies of low-temperature plasma-produced graded oxide-silicate-silica layers of titanium" (cited by applicant in IDS).

The teachings of Smart et al. as applied to claims 46 and 66 are as stated above.

Smart et al. fail to teach increasing the ratio of organosilane to air in the plasma to form the graded layers as required by claims 47 and 67.

Stevenson et al. discloses a process of forming graded layers of oxide-silicate-silica on titanium substrates where the silicate-silica layers are formed by exposing the substrate to a tetraethoxysilane and air plasma where the silicon concentration is increased over time to shift from a silicate structure to a silica structure on the surface of the substrate (see pages 1030 "Air/water/tetraethoxysilane vapor plasma reactions and page 1032).

It would have been obvious to one having ordinary skill in the art to modify the process of Smart et al. to include the step of gradually increasing the concentration of tetraethoxysilane in the plasma over time as taught by Stevenson et al. in order to form the graded silicate-silica layers as desired with improved bonding.

As to claim 50 and 70, the coating formed is a type II silica coating since initially a low concentration of TEOS is used (see Stevenson et al. pg 1032).

Allowable Subject Matter

5. Claims 51, 52, 71 and 72 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The prior art discloses using organosilane source at a temperature of 40C but fails to teach or suggest the use of the organosilane source at temperatures of 8C in order to deposit the graded composite silica or how the temperature of the source would be adjusted to such a temperature and expect successful results in provided the desired silica layer. The applicant's disclosure states using such a temperature allows a certain type of silica to be formed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CACHET I. SELLMAN whose telephone number is (571)272-0691. The examiner can normally be reached on Monday through Friday, 7:00 - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Timothy Meeks can be reached on 571-272-1423. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Cachet I Sellman
Examiner
Art Unit 1715

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